

RECEIVED
CENTRAL FAX CENTER

DEC 21 2006

REMARKS

Claims 1-19 are pending in the application and claims 2, 11-13, and 16 are withdrawn by the Office from consideration. Claims 1, 6, 14, and 15 are in independent form. The final Office action (mailed August 1, 2006) rejected claims 1, 3-10, 14, 15, and 17-19 as allegedly being anticipated by U.S. Patent No. 5,690,619 ("Erskine").

Claim Amendments

Claim 14 is currently amended to correct typographical errors. Claims 1 and 15 are currently amended to remedy a lack of antecedent basis by removing the word 'insertion.' Claim 6 is currently amended to correct a typographical error and more completely claim the invention. Claim 15 is reverted to its original form by replacing 'substantially permanently' with 'fixedly.'

Drawings

The final Office action appears to repeat the drawing objection made in the non-final Office action (mailed November 3, 2005) despite amendments the Applicants made to the specification in its response (mailed May 3, 2006) to the non-final Office action. Specifically, the Applicants amended page 26, line 18 by removing reference numeral 725 to eliminate the need for the requested drawing change. The final Office action simply repeats the drawing objection (e.g., reference numeral 725 on page 16, line 18) without further explanation. The Applicants first note that page 16, line 18 contains no reference to numeral 725, but instead refers to needle 420. FIGS. 12-16 include reference numeral 420. Next, the Applicants believe that the amendments to the specification made on May 3, 2006 obviate a possible drawing objection based on page 26, line 18. Accordingly, the Applicants respectfully request withdrawal of this objection.

Page 9 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

BEST AVAILABLE COPY

*Erskine Rejection – 102(b)*Claims 1-5 and 15-21

Claims 1, 3-10, 14, 15, and 17-19 stand rejected as allegedly being anticipated by Erskine. There are several reasons this anticipation rejection should be withdrawn.

First, claim 1 refers to "a needle retainer fixedly connected with the needle." In addition, claim 15 is currently amended to refer to "a needle retainer fixedly connected with the needle." By way of example, in the present application

needle retainer 740 is configured similarly to the needle retainer 640 described in the previous embodiment. The needle retainer 740 comprises an elongated resiliently flexible arm fixedly connected with the needle 730. The forward end of the needle retainer projects through an opening at the forward end of the housing adjacent the tip 722. The forward portion 746 of the needle retainer engages the side of the catheter hub 772. Similar to the previous embodiment, the catheter hub 772 wedges the needle retainer arm radially outwardly so that a ridge 745 on the arm engages a lip 724 formed by the opening at the forward end of the housing. Accordingly, when the catheter 770 is removed from the device 710, the needle retainer 740 deflects inwardly to release the needle 730. The spring then propels the needle rearwardly into the housing 720. As shown in FIG. 27, the housing is elongated so that the entire length of the needle and the flashback chamber is enclosed within the housing in the retracted position.

Specification, page 25, line 23 through page 26, line 5.

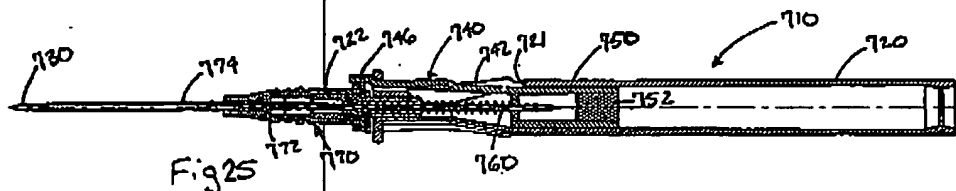


FIG. 25 of the Present Application

Fig 27

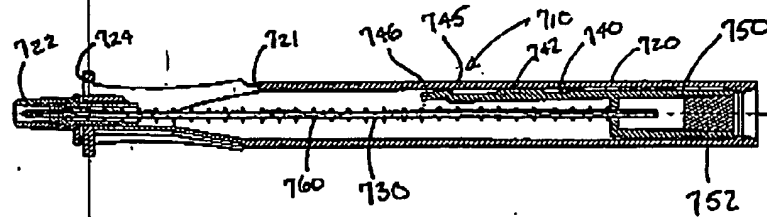


FIG. 27 of the Present Application

By way of another example, the flashback chamber 650 (similar to flashback chamber 750) and the needle retainer 640 (similar to needle retainer 740) are integrally formed as a unitary structure. The two elements are fixedly attached to the needle (e.g., needle 730) by an adhesive such as UV curable epoxy. Specification, page 23, lines 16-18.

The Office action alleges that latch 250 of Erskine anticipates the needle retainer of claims 1 and 15. To better understand the distinctions between claims 1 and 15 and Erskine, portions of Erskine will be explored. In Erskine, latch 250 pivots about point 251 in a cantilever fashion and is biased away from needle hub 221. Foot 252 is held in slot 225 of needle hub 221 by one of the longitudinally extending rails 269. As needle 20 is removed from catheter 10, the longitudinally extending rail holding foot 252 in slot 225 will move away from engagement with foot 252. With nothing holding foot 252 in slot 225 against its bias, foot 252 will move away from slot 225, allowing spring 40 to urge needle hub 221 (and thus needle 20) away from the distal end of barrel 230. Col. 5, lines 12-24.

FIG-7

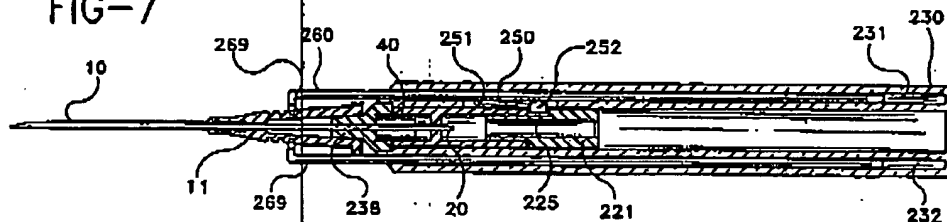


FIG. 7 of Erskine

FIG-8

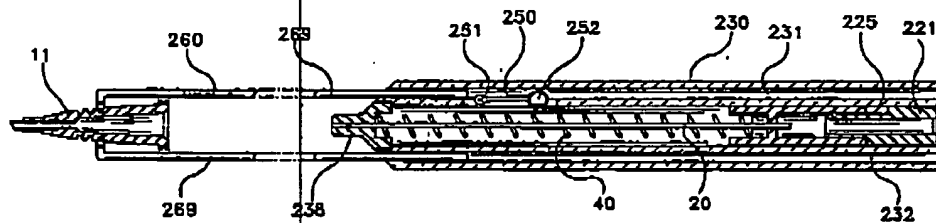


FIG. 8 of Erskine

Latch 250 of Erskine is not fixedly connected to needle 20. In fact, in Erskine latch 250 is not even connected to needle 20. The mere fact that foot 252 of latch 250 touches needle hub 221 (and indirectly needle 20) is not the same as latch 250 being fixedly connected to needle 20. In addition, if latch 250 was fixedly connected to needle 20, the needle retraction system of Erskine would be inoperable. Instead of retracting needle 20 as shown in FIG. 8 of Erskine, needle 20 would remain exposed as shown in FIG. 7 of Erskine.

Next, new claims 20 and 21 (which depend from claims 1 and 15 respectively) refer to the "elongated arm pivot[ing] about the needle retainer." The Office action does not indicate where Erskine discloses "a needle retainer . . . comprising an elongated arm engaging the catheter" and therefore fails to make a *prima facie* case of anticipation (quoting claims 1 and 15). Assuming *arguendo* that latch actuator 260 reads on this portion of claims 1 and 15, latch actuator 260 does not pivot about latch 250. Instead, latch 250 pivots about point 251, which appears to be anchored to barrel 230.

Furthermore, even assuming *arguendo* that needle hub 221 read on the "needle retainer" portion of claims 1 and 15 (instead of latch 250), needle hub 221 of Erskine does not "compris[e] an elongated arm engaging the catheter." (quoting claims 1 and 15). In fact, needle hub 221 does not have any portion engaging catheter 10. Instead, in Erskine, the push off tab 268 of latch actuator 260 (e.g., two longitudinally extending rails 269 and push off tab 268) snaps over catheter hub 11. Col. 4, line 66 through col. 5, line 6.

For at least the foregoing reasons, claims 1 and 15 are patentable over Erskine. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

Claims 2-5 and 20 incorporate all of the limitations of claim 1 and claims 16-19 and 21 incorporate all of the limitations of claim 15. Claims 2-5 and 16-21 are therefore patentable over Erskine for at least the reasons discussed *supra* and the Applicants' response to the non-final Office action. Accordingly, the Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

Claims 6-13

Claim 6, as amended, refers to "an exposed surface manually operable to delay retraction of an inserted needle by retaining the needle retainer in the latched position." The Office action alleges that latch actuator 260 (e.g., the two longitudinally extending rails 269 and push off tab 268) read on "an exposed surface." It is not possible under any conceivable circumstance for latch actuator 260 of Erskine to "delay retraction of an inserted needle by retaining the needle retainer in the latched position."

For example, preventing needle 20 of Erskine from retracting into barrel 230 requires rails 269 to continue holding foot 252 in slot 225 (e.g., preventing latch 250 from being actuated). There is no way to remove catheter hub 11 from needle 20 (while keeping rails 269 in position to hold foot 252) without first bending rails 269 to an extreme angle while needle 20 is inserted into a patient's fragile vein. This may not only cause internal bleeding, but may actually tear apart the vein as needle 20 moves in response to rails 269 being forcibly deformed. This hardly appears to be a procedure medical professionals would perform.

For at least the foregoing reasons, claim 6 is patentable over Erskine. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

Claims 7-13 incorporate all of the limitations of claim 6 and are therefore patentable over Erskine for at least the reasons discussed *supra* and the Applicants' response to the non-final Office action. Accordingly, the Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

Page 13 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

Claim 14

Neither the non-final Office action nor the final Office action have established a *prima facie* case of anticipation with respect to claim 14. In fact, the Office actions have not even attempted to show how Erskine reads on claim 14. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

New Claims 20 and 21

New claims 20 and 21 are submitted to more completely claim the invention.

Election/Restrictions

The final Office action acknowledges that claims 1 and 15 link Species I-XII and claim 6 links Species IX-XII. Based on the previous discussion, the Applicants submit that claims 1, 6, and 15 are allowable. Accordingly, the Applicants respectfully request that the Office withdraw the restriction of claims 2, 11-13, and 16 and examine the same.

Page 14 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

RECEIVED
CENTRAL FAX CENTER

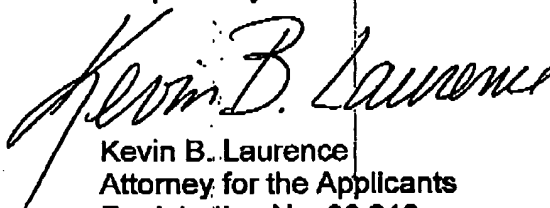
DEC 21 2006

CONCLUSION

In light of the foregoing, the Applicants believe that this application is in form for allowance. The Examiner is encouraged to contact the Applicants' undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

DATED this 21ST day of December, 2006.

Respectfully submitted,



Kevin B. Laurence
Attorney for the Applicants
Registration No. 38,219

STOEL RIVES LLP
One Utah Center
201 South Main Street, Suite 1100
Salt Lake City, Utah 84111
Telephone: (801) 328-3131
Facsimile: (801) 578-6999

Page 15 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

RECEIVED
CENTRAL FAX CENTER
DEC 21 2006

REMARKS

Claims 1-19 are pending in the application and claims 2, 11-13, and 16 are withdrawn by the Office from consideration. Claims 1, 6, 14, and 15 are in independent form. The final Office action (mailed August 1, 2006) rejected claims 1, 3-10, 14, 15, and 17-19 as allegedly being anticipated by U.S. Patent No. 5,690,619 ("Erskine").

Claim Amendments

Claim 14 is currently amended to correct typographical errors. Claims 1 and 15 are currently amended to remedy a lack of antecedent basis by removing the word 'insertion.' Claim 6 is currently amended to correct a typographical error and more completely claim the invention. Claim 15 is reverted to its original form by replacing 'substantially permanently' with 'fixedly.'

Drawings

The final Office action appears to repeat the drawing objection made in the non-final Office action (mailed November 3, 2005) despite amendments the Applicants made to the specification in its response (mailed May 3, 2006) to the non-final Office action. Specifically, the Applicants amended page 26, line 18 by removing reference numeral 725 to eliminate the need for the requested drawing change. The final Office action simply repeats the drawing objection (e.g., reference numeral 725 on page 16, line 18) without further explanation. The Applicants first note that page 16, line 18 contains no reference to numeral 725, but instead refers to needle 420. FIGS. 12-16 include reference numeral 420. Next, the Applicants believe that the amendments to the specification made on May 3, 2006 obviate a possible drawing objection based on page 26, line 18. Accordingly, the Applicants respectfully request withdrawal of this objection.

Page 9 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

BEST AVAILABLE COPY

*Erskine Rejection – 102(b)*Claims 1-5 and 15-21

Claims 1, 3-10, 14, 15, and 17-19 stand rejected as allegedly being anticipated by Erskine. There are several reasons this anticipation rejection should be withdrawn.

First, claim 1 refers to "a needle retainer fixedly connected with the needle." In addition, claim 15 is currently amended to refer to "a needle retainer fixedly connected with the needle." By way of example, in the present application

needle retainer 740 is configured similarly to the needle retainer 640 described in the previous embodiment. The needle retainer 740 comprises an elongated resiliently flexible arm fixedly connected with the needle 730. The forward end of the needle retainer projects through an opening at the forward end of the housing adjacent the tip 722. The forward portion 746 of the needle retainer engages the side of the catheter hub 772. Similar to the previous embodiment, the catheter hub 772 wedges the needle retainer arm radially outwardly so that a ridge 745 on the arm engages a lip 724 formed by the opening at the forward end of the housing. Accordingly, when the catheter 770 is removed from the device 710, the needle retainer 740 deflects inwardly to release the needle 730. The spring then propels the needle rearwardly into the housing 720. As shown in FIG. 27, the housing is elongated so that the entire length of the needle and the flashback chamber is enclosed within the housing in the retracted position.

Specification, page 25, line 23 through page 26, line 5.

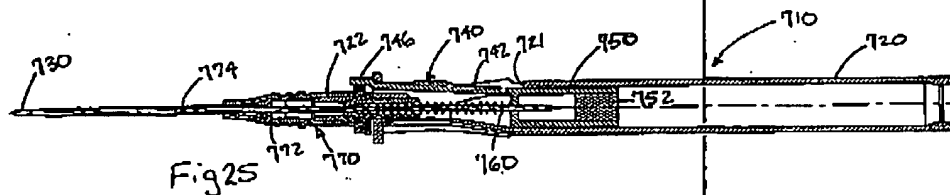


FIG. 25 of the Present Application

Fig 27

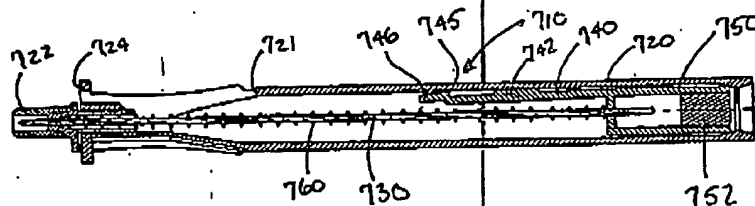


FIG. 27 of the Present Application

By way of another example, the flashback chamber 650 (similar to flashback chamber 750) and the needle retainer 640 (similar to needle retainer 740) are integrally formed as a unitary structure. The two elements are fixedly attached to the needle (e.g., needle 730) by an adhesive such as UV curable epoxy. Specification, page 23, lines 16-18.

The Office action alleges that latch 250 of Erskine anticipates the needle retainer of claims 1 and 15. To better understand the distinctions between claims 1 and 15 and Erskine, portions of Erskine will be explored. In Erskine, latch 250 pivots about point 251 in a cantilever fashion and is biased away from needle hub 221. Foot 252 is held in slot 225 of needle hub 221 by one of the longitudinally extending rails 269. As needle 20 is removed from catheter 10, the longitudinally extending rail holding foot 252 in slot 225 will move away from engagement with foot 252. With nothing holding foot 252 in slot 225 against its bias, foot 252 will move away from slot 225, allowing spring 40 to urge needle hub 221 (and thus needle 20) away from the distal end of barrel 230. Col. 5, lines 12-24.

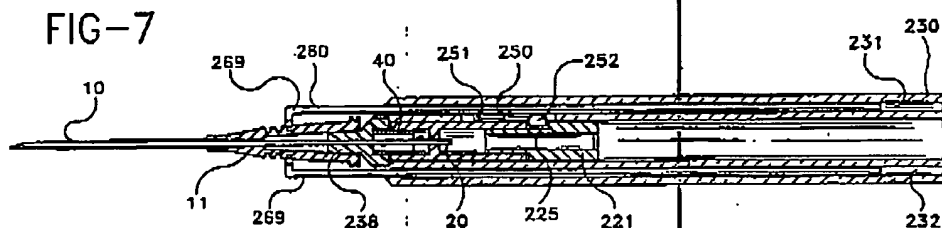


FIG. 7 of Erskine

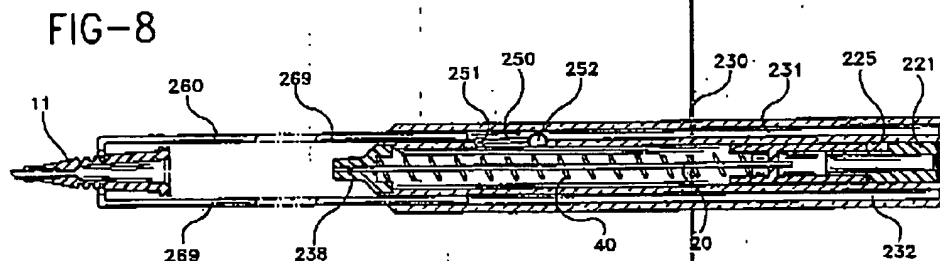


FIG. 8 of Erskine

Latch 250 of Erskine is not fixedly connected to needle 20. In fact, in Erskine latch 250 is not even connected to needle 20. The mere fact that foot 252 of latch 250 touches needle hub 221 (and indirectly needle 20) is not the same as latch 250 being fixedly connected to needle 20. In addition, if latch 250 was fixedly connected to needle 20, the needle retraction system of Erskine would be inoperable. Instead of retracting needle 20 as shown in FIG. 8 of Erskine, needle 20 would remain exposed as shown in FIG. 7 of Erskine.

Next, new claims 20 and 21 (which depend from claims 1 and 15 respectively) refer to the "elongated arm pivot[ing] about the needle retainer." The Office action does not indicate where Erskine discloses "a needle retainer . . . comprising an elongated arm engaging the catheter" and therefore fails to make a *prima facie* case of anticipation (quoting claims 1 and 15). Assuming *arguendo* that latch actuator 260 reads on this portion of claims 1 and 15, latch actuator 260 does not pivot about latch 250. Instead, latch 250 pivots about point 251, which appears to be anchored to barrel 230.

Furthermore, even assuming *arguendo* that needle hub 221 read on the "needle retainer" portion of claims 1 and 15 (instead of latch 250), needle hub 221 of Erskine does not "compris[e] an elongated arm engaging the catheter." (quoting claims 1 and 15). In fact, needle hub 221 does not have any portion engaging catheter 10. Instead, in Erskine, the push off tab 268 of latch actuator 260 (e.g. two longitudinally extending rails 269 and push off tab 268) snaps over catheter hub 11. Col. 4, line 66 through col. 5, line 6.

For at least the foregoing reasons, claims 1 and 15 are patentable over Erskine. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

Claims 2-5 and 20 incorporate all of the limitations of claim 1 and claims 16-19 and 21 incorporate all of the limitations of claim 15. Claims 2-5 and 16-21 are therefore patentable over Erskine for at least the reasons discussed *supra* and the Applicants' response to the non-final Office action. Accordingly, the Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

Claims 6-13

Claim 6, as amended, refers to "an exposed surface manually operable to delay retraction of an inserted needle by retaining the needle retainer in the latched position." The Office action alleges that latch actuator 260 (e.g., the two longitudinally extending rails 269 and push off tab 268) read on "an exposed surface." It is not possible under any conceivable circumstance for latch actuator 260 of Erskine to "delay retraction of an inserted needle by retaining the needle retainer in the latched position."

For example, preventing needle 20 of Erskine from retracting into barrel 230 requires rails 269 to continue holding foot 252 in slot 225 (e.g., preventing latch 250 from being actuated). There is no way to remove catheter hub 11 from needle 20 (while keeping rails 269 in position to hold foot 252) without first bending rails 269 to an extreme angle while needle 20 is inserted into a patient's fragile vein. This may not only cause internal bleeding, but may actually tear apart the vein as needle 20 moves in response to rails 269 being forcibly deformed. This hardly appears to be a procedure medical professionals would perform.

For at least the foregoing reasons, claim 6 is patentable over Erskine. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

Claims 7-13 incorporate all of the limitations of claim 6 and are therefore patentable over Erskine for at least the reasons discussed *supra* and the Applicants' response to the non-final Office action. Accordingly, the Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

Page 13 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

Claim 14

Neither the non-final Office action nor the final Office action have established a *prima facie* case of anticipation with respect to claim 14. In fact, the Office actions have not even attempted to show how Erskine reads on claim 14. Accordingly, the Applicants respectfully traverse and request withdrawal of the rejection.

New Claims 20 and 21

New claims 20 and 21 are submitted to more completely claim the invention.

Election/Restrictions

The final Office action acknowledges that claims 1 and 15 link Species I-XII and claim 6 links Species IX-XII. Based on the previous discussion, the Applicants submit that claims 1, 6, and 15 are allowable. Accordingly, the Applicants respectfully request that the Office withdraw the restriction of claims 2, 11-13, and 16 and examine the same.

Page 14 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

RECEIVED
CENTRAL FAX CENTER

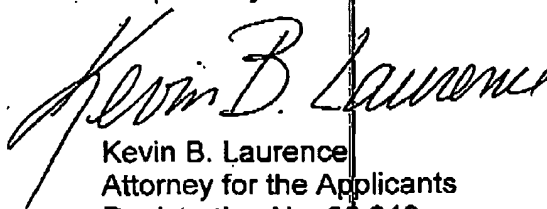
DEC 21 2006

CONCLUSION

In light of the foregoing, the Applicants believe that this application is in form for allowance. The Examiner is encouraged to contact the Applicants' undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

DATED this 21ST day of December, 2006.

Respectfully submitted,



Kevin B. Laurence
Attorney for the Applicants
Registration No. 38,219

STOEL RIVES LLP
One Utah Center
201 South Main Street, Suite 1100
Salt Lake City, Utah 84111
Telephone: (801) 328-3131
Facsimile: (801) 578-6999

Page 15 of 15

U.S. Patent Application Serial No. 10/727,363
Amd. and Response dated December 21, 2006

SaltLake-294359.1 0099999-00001

BEST AVAILABLE COPY